2320 NW 66TH COURT
GAINESVILLE, FL 32653
352 377-1140
FAX 352-378-2617

DEC 2 7 2005

K052787

Exactech® Inc.
AcuMatch 12/14 Cemented Femoral Stems
Novation 12/14 Cemented Femoral Stems
510(k) Summary of Safety and Effectiveness
Special 510(k)

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: **(352) - 377 - 1140**
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FDA Establishment Number 1038671

Contact: **Bennie Gladdish**
Hip Systems Manager/Principal Engineer

Date: **September 27, 2005**

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Trade or proprietary or model name(s):

AcuMatch 12/14 C-Series Cemented Femoral Stems (Size 1-6)
AcuMatch 12/14 L-Series Cemented Femoral Stems (Size 1-5)
Novation Cemented Femoral Stems (Size 9,11,13,15,17)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K023646	AcuMatch 12/14 C-Series Cemented Femoral Stems (Size 1-6)	Exactech, Inc.
K001335	AcuMatch 12/14 L-Series Cemented Femoral Stems (Size 2-5)	
K011218	AcuMatch 12/14 L-Series Cemented Femoral Stems (Size 1)	

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation. Press-fit components without hydroxyapatite (HA) coating may also be used with bone cement at the discretion of the surgeon.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Special 510(k) Modifications
The AcuMatch 12/14 C-Series Cemented femoral stems were modified from the predicate as follows:

- The femoral head/neck taper geometry was modified from Exactech's proprietary taper design to the "12/14 Euro-Style" threadform taper design

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- The femoral neck length was decreased by 4mm
- The femoral neck geometry was shifted medially by 1.5 mm
- The geometry of the insertion hole feature was modified from a dimple to the oblong slot.
- "12/14" Laser-etching was added to the face of the femoral stem taper

The AcuMatch 12/14 L-Series Cemented femoral stems were modified from the predicate as follows:

- The femoral head/neck taper geometry was modified from Exactech's proprietary taper design to the "12/14 Euro-Style" threadform taper design
- The femoral neck length was decreased by 4mm
- The femoral neck geometry was shifted medially by 1.5 mm
- The geometry of the insertion hole feature was modified from a dimple to the oblong slot.
- "12/14" Laser-etching was added to the face of the femoral stem taper.
- A cobra flange geometry was added
- The material specifications for the L-Series cemented stem were changed from cast Co-28Cr-6Mo (ASTM F75) to forged Co-28Cr-6Mo (ASTM F799).

The Novation Cemented femoral stems were modified from the predicate as follows:

- The femoral head/neck taper geometry was modified from Exactech's proprietary taper design to a "12/14 Euro-Style" threadform taper design
- The trapezoidal cross-sectional area was modified to a circulo-trapezoidal geometry.
- A change to the sizing range and differential.
- The insertion hole feature was changed from a spherical dimple to the oblong slot
- A "12/14" Laser-etching was added to the face of the femoral stem taper.

Conclusion:

Testing and engineering evaluations were conducted to verify that the performance of the new Exactech AcuMatch 12/14 Cemented Femoral Stems and Novation Cemented Stems would be adequate for anticipated *in vivo* use. This includes empirical testing and engineering analyses. Based on successful results we conclude that the proposed devices are substantially equivalent to Exactech's predicate femoral stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Ms. Maritza Elias
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K052787
Trade/Device Names: AcuMatch 12/14 Cemented Femoral Stems; Novation 12/14 Cemented Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO, JDI
Dated: November 22, 2005
Received: December 8, 2005

Dear Ms. Elias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

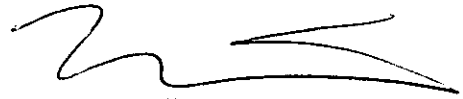
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exactech®, Inc.

AcuMatch 12/14 Cemented Femoral Stems
Novation 12/14 Cemented Femoral Stems

Indications for Use

510(k) Number: K052787

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

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- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

CONTRAINDICATIONS

Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system. The L-Series unipolar and bipolar endoprostheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

Prescription Use ___X___ **or** **Over the Counter Use** _____

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

09/27/05

510(k) Number K052787